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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LINDA S. MANSFIELD, MARY G. ROSSANO,
ALICE J. MURPHY, and RUTH A. VRABLE

Appeal 2008-1674
Application 09/513,086
Technology Center 1600

Decided: March 17, 2008

Before ERIC GRIMES, LORA M. GREEN, and RICHARD M. LEBOVITZ
Administrative Patent Judges.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 4, 13, 46, and 50. We have jurisdiction under 35 U.S.C. § 6(b). Claims 4 and 13 are representative of the claims on appeal, and reads as follows:

4. A composition consisting of a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona* in a pharmaceutically acceptable carrier.

13. A method for treating an equine with *Sarcocystis neurona* infection, comprising:

(a) providing a composition consisting of a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona* in a pharmaceutically acceptable carrier; and

(b) inoculating the equine with the composition to treat the equine with the *Sarcocystis neurona* infection.

We reverse.

DISCUSSION

Claims 4, 13, and 46 stand rejected under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the [S]pecification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." (Ans.[1] 3.) This is a new matter rejection (*id.*).

The Examiner asserts that the terms "isolated" and "naturally occurring" are not supported by the disclosure as filed (*id.*). According to the Examiner, the only support for "isolated" would be in the context of a recombinant protein (*id.* at 4). The Examiner further notes that "there is no literal support for isolating the 16 and 30 kDa proteins directly from *Sarcocystis neurona* as a contemplated part of the invention." (*Id.*) The

[1] All references to the Answer (Ans.) are to the Examiner's Answer mailed October 17, 2006.

Examiner notes moreover that there does not appear to be support for "naturally occurring," asserting that "the literal support for this embodiment can not be found, in particular in the context of an 'antigen' versus the protein itself that exists in nature." (*Id.*)

The Examiner notes, however, "that it appears that the [S]pecification would support *inter alia* 'consisting' since it does contemplate two proteins in a composition." (*Id.* at 3.)

The burden is on the examiner to set forth a prima facie case of unpatentability. *See In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996). The disclosure as originally filed need not provide "*in haec verba* support for the claimed subject matter at issue," rather, the disclosure should convey to one skilled in the art that the inventor had possession of the invention at the time of filing. *Purdue Pharma L.P. v. Faulding Pharmaceutical Co.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (citations omitted).

We find that the disclosure as filed would convey to one skilled in the art that the inventors had possession of a composition consisting of naturally occurring 16 (±4) kDa protein antigen and naturally occurring 30 (±4) kDa protein antigen, isolated from *Sarcocystis neurona*, as well as methods of using such compositions.

The Specification discloses that an object of the invention is to provide a vaccine which comprises a 16 (±4) kDa protein antigen and a 30 (±4) kDa of *Sarcocystis neurona*. (Spec. 10, ll. 25-29.) The Specification teaches further that the "active immunity is provided by a vaccine that consists of the isolated 16 (±4) kDa antigen and/or 30 (±4) kDa antigen or the 16 (±4) kDa antigen and/or 30 (±4) kDa antigen as a fusion polypeptide." (*Id.* at 15, ll. 30-35.) The Specification notes further that in

one embodiment, "the antigen is a recombinant polypeptide . . . ." (*Id.* at 5, ll. 30-31).

As noted by Appellants (App. Br.[2] 11), Example 1 is drawn to the production of monoclonal antibodies that recognize the 16 (±4) kDa antigen and/or 30 (±4) kDa antigen of *Sarcocystis neurona* (Spec. 33, l. 20). In the method, *Sarcocystis neurona* is cultured and merozoites were harvested (*Id.* at ll. 25-29). The 16 (±4) kDa antigen and the 30 (±4) kDa antigen "were purified by methods known to the art for purifying antigens, i.e., the 16 (±4) kDa antigen and/or 30 (±4) kDa antigen were purified from merozoites by two-dimensional polyacrylamide gel electrophoresis." (*Id.* at ll. 25-34).

Thus, the Specification discloses naturally occurring 16 (±4) kDa antigen and 30 (±4) kDa antigen isolated from *Sarcocystis neurona* (Spec. 33). Based on that disclosure, along with the fact that the Specification teaches that an object of the invention is to provide a vaccine which comprises a 16 (±4) kDa protein antigen and a 30 (±4) kDa of *Sarcocystis neurona* (*id.* at 10), of which the recombinant form is just one embodiment, the ordinary artisan would understand that the inventors had possession of the invention of claims 4, 13, and 46 at the time of filing, and the rejection is reversed.

Claims 4, 13, and 46 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. According to the Examiner, "[t]o the extent that the claimed compositions and/or methods are not described in the instant disclosure," they are not enabled as "a disclosure cannot teach one to make or use something that has not been described." (Ans. 4.)

[2] All references to the Appeal Brief (App. Br.) are to the Supplemental Brief, date stamped June 29, 2006.

Because this rejection is based on the new matter rejection discussed above, and since we reversed that rejection, we reverse this rejection as well.

Claims 4, 13, 46, and 50 stand rejected under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the [S]pecification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." (Ans. 5.)

The Examiner asserts that while "Western blots of all of the proteins of *Sarcocystis neurona* have been separated on a two dimensional gel demonstrating multiple spots representing the forms of the proteins that are naturally occurring . . . , neither the present [S]pecification nor the art of record at the time of filing has provided any specific information about the primary sequence of the protein antigens claimed." (*Id.*)

The function of the written description requirement of the first paragraph of 35 U.S.C. § 112 is to ensure that the inventor has possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him. *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976), *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). In establishing a basis for a rejection under the written description requirement, the Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263.

Here, Appellants are not claiming protein antigens of a certain amino acid sequence, but are claiming compositions and methods that require a single naturally occurring 16 (±4) kDa protein antigen isolated from *Sarcocystis neurona* and a single naturally occurring 30 (±4) kDa protein antigen isolated from *Sarcocystis neurona*. As noted by Appellants:

> The 16 (±4) and 30 (±4) kDa antigens are described in the specification by their physical properties, not merely by their function. The 16 (±4) and 30 (±4) kDa antigens are described by their source (isolated from *Sarcocystis neurona*), by their molecular weight as determined by SDS gel electrophoresis, by their ability to bind particular antibodies in antisera from horses infected with *Sarcocystis neurona*, and by their ability to bind monoclonal antibodies prepared against them. These physical properties convey sufficient information about the antigens to distinguish them from the other proteins of *Sarcocystis neurona*.

(App. Br. 17.) Thus, Appellants need not provide an amino acid sequence to meet the written description requirement of 35 U.S.C. § 112, first paragraph, and the rejection is reversed.

CONCLUSION

In summary, we reverse the rejection of claims 4, 13, and 46 under 35 U.S.C. § 112, first paragraph, as containing new matter; the rejection of claims 4, 13, and 46 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement; and the rejection of claims 4, 13, 46, and 50 under 35 U.S.C. § 112, first paragraph, for failing to meet the written description requirement.

REVERSED

Ssc:

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